OCT 16 2006

510(k) Submission

Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting a 510(k) Summary of Safety and Effectiveness for the ConMed Linvatec Instrument Sterilization Tray.

510(k) # K052992

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Elizabeth Paul
Manager, Regulatory Affairs
(727) 399-5234 Telephone
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C. Device Name

Trade Name: Instrument Sterilization Tray

Common Name: Instrument Sterilization Tray

Classification Name: Accessory to Sterilization Wrap, CFR 880.6850

Proposed Class/Device: Class II

Product Code: FRG

D. Predicate/Legally Marketed Devices

K993535 – MetaPak Multi-Purpose Instrument Tray – Riley Medical, Inc.
K023658 - Sterilization cases, trays and cassettes – Carr Medical Products
K944025 - MetaPak Multi-Purpose Instrument Tray – Riley Medical, Inc.

E. Device Description

The ConMed Linvatec sterilization trays consist of base trays, lids and internal individualized insert trays. Each tray is composed of multiple pieces and is designed to be integrated into a single unit, which will contain and protect the interior components during sterilization. The interior structures of the tray have the ability to separately hold each individual piece during the entire duration they are in contact with the tray.

The rigid, multi piece tray holds medical device apparatus and accessories before, during and after the sterilization process. The tray set has a locking lid to contain products, which is held to the base by latches designed to fasten the lid to the base not allowing the two to separate. The trays are designed to fit any standard autoclave, which allows it to be effective for sterilization and be able to withstand the environment of repeated steam sterilization cycles in a normal operating room.

The tray is designed to allow repeated sterilization cycles. Though these trays are reusable they will not be serviced or repaired. Like the outer containing trays, the interior trays with individual containment custom brackets have been developed to withstand repeated use and will not be serviced or repaired. These custom brackets are made of materials that do not contaminate the tray or any of the parts or pieces contained within the tray.

The lid, base and insert for the proposed trays are made of Radel R-5000. This material is a polymer resin produced by Solvay Advanced Polymers, LLC. This material is identical to the Radel used in the predicate device cleared under K993535. Attachment I includes the material composition for the Radel R-5000.

The latches, which secure the lid to the base, are constructed of 300 Series Stainless Steel, identical to the stainless steel in the predicate devices cleared under K993535 and K944025.

The instruments to be sterilized in the proposed trays are all non-porous devices and including instruments such as suture snares, various hooks, graspers, scissors, knot pushers, probes, extractors, drivers, rasps, obturators, etc.
Each tray includes brackets and containment mats which are made of a biomedical grade silicone. These are used to secure the instruments during transport, sterilization and storage. The drawings in Attachment III include the brackets and mats.
Additional device characteristics can be found in the chart included as Attachment A of this 510(k) Summary.
The brackets and containment mats are both constructed from biomedical grade silicone which has been manufactured to meet FDA CFR 177.2600. This material is identical to the predicate devices cleared under K993535 and K944025.

F. Intended Use

Intended Use

The ConMed Linvatec® Instrument Sterilization Trays are for loading surgical instruments in order to conveniently organize, sterilize, transport and store the instrument between uses.
ConMed Linvatec® Instrument Sterilization Trays can be used in a steam sterilization cycles. The validated sterilization cycles are provided in Table II.

Important Notes

The cycles were validated using Kimguard (Kimberly Clark) wrap. The sterilization exposure times are extended. Please refer to Table 2 for cycle times. Only sterilization wraps cleared by FDA for extended sterilization exposure times should be used with these trays. The sterilized contents are for immediate use and should not be stored for any duration.

The trays are intended for sterilization of non-porous loads, e.g. hooks, grassers, scissors, knot pushers, probes, extractors, drivers, rasps, obdurators, etc.

The trays are not intended to be stacked during the sterilization process

G. Substantial Equivalence

The ConMed Linvatec Instrument Sterilization Tray is substantially equivalent in materials and is similar in intended use and design to the below identified predicate devices. The proposed Instrument Sterilization Tray and the predicate devices are used for storage, transport, and sterilization of surgical instruments between uses. Both the proposed and predicate devices are suitable for use in steam sterilization processes.

The ConMed Linvatec Instrument Sterilization Tray will be offered in a combination of various metals and plastics.

There are no significant differences between the proposed device and the predicate devices other than various tray sizes and layout of custom containment brackets. Also see Attachment B of this 510(k) summary for further details.

Substantially Equivalent Predicate Marketed Device:

K993535 – MetaPak Multi-Purpose Instrument Tray – Riley Medical, Inc.
K023658 - Sterilization cases, trays and cassettes – Carr Medical Products
K944025 - MetaPak Multi-Purpose Instrument Tray – Riley Medical, Inc.

H. Technological Characteristics

The design and materials used in of the ConMed Linvatec Instrument Sterilization Trays, a perforated plastic tray with a stainless steel latch and silicone containment brackets, that allows free steam passage is the substantially equivalent to the predicate devices. All trays have various dimensions such that the proposed trays and the predicates devices are substantially equivalent in size and volume. The sterilization validation of all trays has met the requirements of the same performance standard, AAMI TIR No.12-1994. The associated procedures for the use of the devices , i.e. the manufacturer's recommended sterilization cycles, are all similar.

I. Summary and Conclusion

The Conmed Linvatec Instrument Sterilization Tray has the same intended use, technological characteristics and performance characteristics as the predicate devices. Thus, the proposed tray does not raise any new issues of safety and efficacy and per the definition under 21 CFR 807.100 is substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Elizabeth M. Paul
ConMed Linvatec
Manager, Regulatory Affairs
11311 Concept Boulevard
Largo, Florida 33773-4908

OCT 16 2006

Re: K052992
Trade/Device Name: ConMed Linvatec Instrument Sterilization Tray
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: September 19, 2006
Received: September 21, 2006

Dear Ms. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052992

Device Name: ConMed Linvatec Instrument Sterilization Tray

Indications for Use:

The ConMed Linvatec Instrument Sterilization Tray is used for loading surgical instruments in order to conveniently organize, sterilize, transport and store the instruments between uses.

The ConMed Linvatec Instrument Sterilization Tray is for use with steam sterilization.
The validated sterilization cycles are provided in Table II.
The cycles were validated using Kimguard (Kimberly Clark).
The sterilization exposure times are extended. Please refer to Table 2 for cycle tines.
Only sterilization wraps cleared by FDA for extended sterilization exposure times should be used with these trays.
The sterilized contents are for immediate use and should not be stored for any duration.

The trays are intended for sterilization of non-porous loads, e.g. hooks, graspers, scissors, knot pushers, probes, extractors, drivers, rasps, obdurators, etc.

Table 1 lists the trays included in this submission.

Table 1 **Tray Characteristics**

Catalog Number	Description	Recommended Max load (lbs.)*	Length (Inches)	Width (Inches)	Depth (Inches)
9895	ROTATOR CUFF STERILATION CASE TRAY	2.54	14.60	9.52	0.82
	ROTATOR CUFF STERILE CASE (BASE)		14.45	9.4	0.4
8217	OSTEOPREP STERILE TRAY (LID)	4.08	20.88	10.13	0.82
	OSTEOPREP STERILE TRAY (BASE)		20.63	9.81	1.19
C6355	SPECTRUM II (LID)	11.90	20.75	9.93	1.116
	SPECTRUM II (UPPER TRAY)		19.75	8.94	1.97
	SPECTRUM II (BASE)		20.46	9.67	4.76

*Includes the weight of the tray.

Table 2

Validated Sterilization Cycles				
Method	**Cycle**	**Minimum Temperature**	**Minimum Exposure**	**Minimum Dry Cycle**
Steam	Pre-vacuum	270°F (132°C)	5 minutes	10 minutes
Steam	Gravity	270°F (132°C)	30 minutes	10 minutes

Prescription Use_____OR

(Part 21 CFR 801 subpart D)

Over-the-Counter Use __X___

(Part 21 CFR 807 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE if NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elaine S. Maykall for S. Murphy

...n Sign-Off)

...n of Anesthesiology, General Hospital,

...ion Control, Dental Devices

...er K052992